## 100 Pine Street, Suite 1250 San Francisco, CA 94111 7 8 9 10 11 12 13 v. 14 15 16 17 18 1. 19 20 21 22 2. 23 24 25 26

27

28

#### GUTRIDE SAFIER LLP

Seth A. Safier (State Bar No. 197427)

seth@gutridesafier.com

Marie A. McCrary (State Bar No. 262670)

marie@gutridesafier.com

Hayley Reynolds (State Bar No. 306427)

hayley@gutridesafier.com

Telephone: (415) 639-9090

Facsimile: (415) 449-6469

Attorneys for Plaintiff

#### UNITED STATES DISTRICT COURT FOR THE

#### NORTHERN DISTRICT OF CALIFORNIA

LYDIA HARVILLE, an individual, on behalf of herself, the general public, and those similarly situated,

Plaintiff.

THREE WISHES FOODS, INC.,

Defendant

CASE NO.

CLASS ACTION COMPLAINT FOR VIOLATION OF THE CALIFORNIA CONSUMERS LEGAL REMEDIES ACT: FALSE ADVERTISING; FRAUD, DECEIT, AND/OR MISREPRESENTATION; UNFAIR **BUSINESS PRACTICES; AND UNJUST ENRICHMENT** 

JURY TRIAL DEMANDED

#### **INTRODUCTION**

- Plaintiff Lydia Harville, by and through her counsel, brings this class action against Defendant Three Wishes Foods, Inc. ("Defendant") to seek redress for its unlawful and deceptive practices in labeling and marketing the Three Wishes brand cereals which make protein claims on the front of the product packages and are unlawfully fortified.
- Consumers are increasingly health conscious and, as a result, many consumers seek foods high in protein. To capitalize on this trend, Defendant prominently claims on the front of its Three Wishes brand cereal product packages that they provide 8g protein per serving and contain "More protein." Consumers, in turn, reasonably expect that each product will actually provide the amount of protein per serving claimed on the front of the product package in a form the body can use.

The Food and Drug Administration ("FDA") prohibits such front label claims

1 2 abo 3 nutri 4 prod 5 FD. 6 amo 7 not 8 are 9 the 10 are 11 hum 12 bod 13 shu 14 was 15 for 16 its 4

3.

- 17
- 19 20

- 21
- 2223
- 24
- 2526
- 2728

- about the amount of protein, unless manufacturers also provide additional information in the nutrition fact panel about how much of the recommended daily value for protein that the product will actually provide. 21 C.F.R. §§ 101.9(c)(7)(i), 101.13(b), (n). That is because the FDA recognizes that (1) when manufacturers tout an amount of protein on the front label, that amount is likely to be material to purchasing decisions, even though reasonable consumers may not know the total amount of protein they need to ingest on a daily basis, and (2) not all proteins are the same in their ability to meet human nutritional requirements, so a simple statement about the number of grams does not actually inform consumers about how much usable protein they are receiving. Some proteins are deficient in one or more of the nine amino acids essential to human protein synthesis and/or are not fully digestible within the human gut. When a human body uses up the least prevalent essential amino acid from a food product, protein synthesis shuts down and all of the remaining amino acids from that protein source degrade mostly into waste. Likewise, whatever portion of a protein source is not digestible is similarly unavailable for protein synthesis. A protein's ability to support human nutritional requirements is known as its "quality."
- 4. The FDA required method for measuring protein quality is called the "Protein Digestibility Corrected Amino Acid Score"—known by its acronym PDCAAS (pronounced Pee-Dee-Kass). It combines a protein source's amino acid profile and its percent digestibility into a discount factor ranging from 0.0 to 1.0 that, when multiplied by the total protein quantity, shows how much protein in a product is actually available to support human nutritional requirements. The regulations term this the "corrected amount of protein per serving." 21 C.F.R. § 101.9(c)(7)(ii). For example, a PDCAAS of .5 means that only half of the protein in that product is actually available to support human protein needs. If the product contained 10 grams total protein per serving, the corrected amount of protein would be only 5 grams per serving. As a result, protein products can vary widely in their ability to support human protein needs—even between two comparator products with the same total protein quantity.

21

22

23

24

25

26

27

28

5. Because consumers are generally unaware about the usability of various proteins and may even be unaware of the total amount of usable protein they should ingest each day, the FDA prohibits manufacturers from advertising or promoting their products with a protein claim unless they have satisfied two requirements. First, the manufacturer must calculate the "corrected amount of protein per serving" based on the quality of the product's protein using the PDCAAS method. Second, the manufacturer must use the PDCAAS computation to provide "\( \frac{1}{2} \) statement of the corrected amount of protein per serving" in the nutrition facts panel ("NFP" "expressed as" a percent daily value ("%DV") and placed immediately adjacent to the statement of protein quantity. 21 C.F.R. § 101.9(c)(7)(i)-(iii). The %DV is the corrected amount of protein per serving divided by the daily reference value for protein of 50 grams. Id. Using the same example of a product containing 10 grams total protein per serving with a PDCAAS of .5, the %DV is 10% (5g/50g). Had all of the protein in the product been useful in human nutrition, the %DV would be 20% (10g/50g). The FDA regulations that govern nutrient content claims are also clear that the manufacturer may not make any front label claims about the amount of protein in the product unless it complies with these two requirements. See 21 C.F.R. § 101.13(b) ("A nutrient content claim[] may not be made on the label...unless the claim is made in accordance with this regulation [i.e., § 101.13]..." and (n) ("[n]utrition labeling in accordance with § 101.8...shall be provided for any food for which a nutrient content claim is made") accord 58 Fed. Reg. 2302, 23310 (manufacturer can only make a "nutrient content claim...on the label or in labeling of a food, provided that the food bears nutrition labeling that complies with the requirements in proposed § 101.9.").

6. The primary protein sources in Defendant's products are chickpea protein, pea protein, and tapioca (which is extracted from cassava). The PDCAAS scores for these proteins are as follows: (i) chickpea – 0.75; (ii) pea – .82; and (iii) tapioca – 0.57, which means Defendant's products will provide nutritionally as little as approximately *half* of the protein quantity claimed. Nevertheless, Defendant failed to provide in the NFP a statement of the corrected amount of protein per serving calculated according to the PDCAAS methodology and expressed as a %DV. Accordingly, the protein claims on the front of the package, such as "8g

protein per serving" are unlawful in violation of parallel state and federal laws because Defendant did not comply with the regulatory requirements for making a protein claim. 21 C.F.R. § 101.9(c)(7)(i), 101.13(b), (n). The failure to include a statement of the corrected amount of protein inside the NFP also rendered the NFP itself unlawful. *Id.* § 101.9(c)(7)(i).

- 7. Where a product makes a protein claim, the NFP is required to contain a statement of the corrected amount of protein per serving calculated according to the PDCAAS methodology and expressed as a %DV. Accordingly, the protein claims on the front of the cereal packages, such as "8g protein per serving," are unlawful in violation of parallel state and federal laws because Defendant did not comply with the regulatory requirements for making a protein claim.
- 8. In addition to being unlawful under 21 CFR §§ 101.9 and 101.13, Defendant's prominent protein claim on the front of the package, in the absence of any statement of the corrected amount of protein per serving expressed as a %DV in the NFP, also is likely to mislead reasonable consumers. Consumers reasonably expect that Defendant's products will actually provide nutritionally the full amount of protein per serving claimed on the front of the package and stated in the protein quantity section of the NFP. But Defendant's products do not do so on account of their low protein quality. Had Defendant included a statement of the corrected amount of protein per serving in the NFP, as it was required to do under the law, it would have revealed that the product provides nutritionally as little as half of their total protein quantity. That information was material to reasonable consumers.
- 9. Additionally, Defendant's protein claim is also misleading because it is stated in the form of a quantitative amount appearing alone, without any information about protein quality. FDA regulations prohibit a manufacturer from stating "the amount or percentage of a nutrient" on the front label if it is "false or misleading in any respect." 21 C.F.R. § 101.13(i)(3). Defendant fails to disclose to consumers that the protein sources in the Three Wishes cereal are low quality and only provide approximately half the protein claimed on the label. This is misleading.

- 10. Defendant's Three Wishes cereals are additionally misbranded within the meaning of section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 343(r)(1)(A)] (the "Act" or the "FDCA") because the addition of protein does not comply with the FDA Fortification Policy, which is binding in these circumstances.
- a model for the rational addition of nutrients to foods." 21 C.F.R. § 104.20. Although recognizing the benefits of adding nutrients to foods, the FDA cautioned that "[the random fortification of foods] could also result in deceptive or misleading claims for certain foods." *Id.* The Fortification Policy provides that "[a]ny claims or statements in the labeling of food about the addition of a vitamin, mineral, or protein to a food shall be made only if the claim or statement is not false or misleading and otherwise complies with the act and any applicable regulations." 21 C.F.R. § 104.20(h).
- 12. The Fortification Policy is made binding where other binding regulations incorporate it by reference. One such circumstance is 21 C.F.R. § 101.54(e). This regulation governs the use of "more" claims, which includes "relative claim[s]" using terms such as "more" to describe the level of a nutrient as compared to a reference food. 21 C.F.R. § 101.54(e)(1)(iii). Among the requirements for the use of these terms is compliance with the Fortification Policy. 21 C.F.R. § 101.54(e)(1)(ii).
- 13. The Products have "more" claims, including "More protein" followed by, for example, "2x more protein than the leading whole grain oat cereal" on the unsweetened flavor. Therefore, the Products must comply with the Fortification Policy. 21 C.FR. § 101.54(e)(1)(ii). However, the Products do not meet any of the four criteria where the FDA permits fortification under the Fortification Policy. *See* 21 C.F.R. § 104.20(b)-(e). Specifically, the scientific community has not recognized a dietary insufficiency of protein; the protein is not added to restore nutrients to levels of the food prior to storage; the protein is not added to balance the vitamin, mineral, and protein content in proportion to the total caloric content; and the protein is not added "to avoid nutritional inferiority" when replacing a traditional food." *Id.* Therefore, the fortification of the Three Wishes cereal violates 21 C.F.R. § 101.54(e) and 21 C.F.R. § 104.20.

14. Defendant's unlawful and misleading protein claims caused Plaintiff and members of the class to pay a price premium for the Three Wishes cereals.

#### **PARTIES**

- 15. Plaintiff Lydia Harville is, and at all times alleged in this Class Action Complaint was, an individual and a resident of Los Gatos, California. Plaintiff Harville makes her permanent home in California and intends to remain in California.
- 16. Defendant Three Wishes Foods, Inc. is a corporation existing under the laws of Delaware, with its principal place of business in New York, New York.

#### **JURISDICTION AND VENUE**

- 17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d)(2). The aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs; and Plaintiff and Defendant are citizens of different states.
- 18. The injuries, damages and/or harm upon which this action is based, occurred or arose out of activities engaged in by Defendant within, affecting, and emanating from, the State of California. Defendant regularly conducts and/or solicits business in, engages in other persistent courses of conduct in, and/or derives substantial revenue from products provided to persons in the State of California. Defendant has engaged, and continues to engage, in substantial and continuous business practices in the State of California.
- 19. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the state of California, including within this District.
- 20. In accordance with California Civil Code Section 1780(d), Plaintiff concurrently files herewith a declaration establishing that, at various times throughout the class period, she purchased Three Wishes cereals in the Unsweetened and Cocoa flavors on Amazon.com and at a Whole Foods retail store in California. (Plaintiff's declaration is attached hereto as Exhibit A.)
  - 21. Plaintiff accordingly alleges that jurisdiction and venue are proper in this Court.

#### **SUBSTANTIVE ALLEGATIONS**

22. Defendant manufactures, distributes, markets, advertises, and sells cereals in a variety of flavors under the brand name "Three Wishes." All the flavors of Three Wishes cereal have packaging that predominately, uniformly, and consistently states on the principal display panel of the product labels that they contain and provide 8 grams of protein per serving and contain "More protein." Plaintiff has attached, as Exhibit B, a non-exhaustive list of the Three Wishes products that make protein claims on the front of the product packages. The products listed in Exhibit B, and any other Three Wishes product that claims a specific amount of protein on the front of its label or makes a "More protein" claim, will hereinafter be referred to as the "Products."

23. The representations that the Products contain and provide a specific amount of



protein per serving and that the Products contain "More protein" were uniformly communicated to Plaintiff and every other person who purchased any of the Products in California. The same

- '/ -CLASS ACTION COMPLAINT

or substantially similar product label has appeared on each Product during the entirety of the Class Period in the general form of the following example:

24. The nutrition facts panel on the back of the Products uniformly and consistently failed to provide any statement of the corrected amount of protein per serving, expressed as a %DV, throughout the Class Period. The nutrition facts panel of the Products has appeared consistently throughout the Class Period in the general form of the following example (from the Three Wishes cereal in Unsweetened flavor):

Nutrition Fac 7 Servings Per Container Serving Size 3/4 cup			
Calories	110		
% Da	illy Value*		
Total Fat 2g	3%		
Saturated Fat 0g	0%		
Trans Fat 0g			
Cholesterol 0mg	0%		
Sodium 100mg	4%		
Total Carbohydrate 15g	5%		
Dietary Fiber 3g	11%		
Total Sugars 0g			
Includes 0g Added Sugars	0%		
Protein 8g			
Vitamin D 0mcg	0%		
Calcium 150mg	10%		
Iron 1.9mg	10%		
Potassium 300mg	6%		
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.			

25. As described in detail below, Defendant's advertising and labeling of the Products as containing and providing specific amounts of protein per serving is unlawful, misleading, and intended to induce consumers to purchase the Products at a premium price, while ultimately failing to meet consumer expectations. The Products' front label protein claims are unlawful because Defendant did not: (1) calculate the "corrected amount of protein per serving" based on the quality of the product's protein using the PDCAAS method; (2) provide a statement of that corrected amount of protein per serving in the NFP, expressed as "DV. 21 C.F.R. § 101.9(c)(7)(i) & (iii); and (3) comply with the FDA's fortification policy. Defendant's

failure to comply with § 101.9 also makes the front label claims unlawful under §§ 101.13(n) and (b). The unlawful front label protein claims and fortification induced consumers to purchase the Products at a premium price. Had Defendant complied with FDA regulations and not included a protein claim on the front label of its Products and not fortified the Products, reasonable consumers would not have purchased them or would have paid less for the Products. The front label protein claims are also false and misleading because they deceive reasonable consumers into believing that a serving of the Products will provide the grams of protein as represented on the label, when in fact, correcting for the Products' poor protein quality through PDCAAS, the amount provided will be approximately half or less because Defendant uses proteins of low biological value to humans in its products, such as chickpea, pea, and tapioca derived proteins.

26. Defendant's failure to provide the required statement of the corrected amount of protein per serving, as well as Defendant's prominent front label protein claims made in the absence of any statement of the corrected amount of protein in the NFP, also deceived and misled reasonable consumers into believing that a serving of the Products will provide the grams of protein represented on the label, when that is not true. Had Defendant complied with the law, the statement of the corrected amount of protein would have revealed the Products provide significantly less protein than claimed because Defendant uses low quality protein in the Products such as chickpea, pea, and tapioca. The absence of this information also allowed Defendant to charge a price premium. Had reasonable consumers been informed of the true amount of protein that the products provided through a statement of the corrected amount of protein per serving, as required by FDA regulations, they would not have purchased or would have paid less for the Products.

#### **Consumer Demand for Protein**

27. Many American consumers are health conscious and seek wholesome, natural foods to keep a healthy diet, so they routinely rely upon nutrition information when selecting and purchasing food items. As noted by FDA Commissioner Margaret Hamburg during an October 2009 media briefing, "[s]tudies show that consumers trust and believe the nutrition

facts information and that many consumers use it to help them build a healthy diet." Indeed, the FDA recommends relying on Nutrition Facts Labels as the primary tool to monitor the consumption of protein.<sup>1</sup>

- 28. Protein is found throughout the body—in muscle, bone, skin, hair, and virtually every other body part or tissue. The health benefits of protein are well studied and wide ranging. Scientific studies have confirmed that protein can assist in weight loss, reduce blood pressure, reduce cholesterol, and control for risk factors for cardiovascular diseases. The National Academy of Medicine recommends that adults get a minimum of .8 grams of protein for every kilogram of body weight per day, or just over 7 grams for every 20 pounds of body weight. For a 140-pound person, that means about 50 grams of protein each day. For a 200-pound person, that means about 70 grams of protein each day.
- 29. The health benefits of protein are just as important, if not more important, for children. Children are in a relative state of constant growth and rely on protein as the building block of muscle, bone, skin, hair, and virtually every other body part or tissue. The National Academies of Science recommends the following amounts of daily intake of protein based on age group: 1-3 years old: 13 g of protein per day; 4-8 years old: 19 g of protein per day; 9-13 years old: 34 g of protein per day.<sup>3</sup>
- 30. Protein *quantity* by itself does not tell the full story of protein from a human nutritional standpoint. A protein's *quality* is also critical because humans cannot fully digest or utilize some proteins. Proteins are not monolithic. They are simply chains of amino acids, and different types of amino acids chained together in different ways will make different types of proteins. Further, the makeup of the protein changes the function of that protein in the body, and certain types of proteins are more easily digested and used by humans than others.

<sup>&</sup>lt;sup>1</sup> FDA Protein Fact Sheet,

https://www.accessdata.fda.gov/scripts/InteractiveNutritionFactsLabel/factsheets/Protein.pdf <sup>2</sup> National Academies of Medicine. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients).* <sup>3</sup> *Id* 

All of a human's proteins are formed through the process of protein synthesis

31.

within their own bodies. That is, although humans consume dietary proteins, they digest those proteins, break them down into their constituent amino acids, and then use those amino acids as building blocks to synthesize the human proteins necessary for life, tissue repair, and other functions. Of the twenty total amino acids, humans can produce only eleven of them on their own. Humans cannot produce, under any circumstances, nine of the amino acids required for protein synthesis. These nine amino acids are called the "essential amino acids" and they must be supplied through the diet.

- All nine essential amino acids are necessary for protein synthesis to take place. Lacking even one essential amino acid will prevent protein synthesis from occurring, and the rest of the proteins will degrade into waste. Accordingly, once the body uses up the limiting essential amino acid from a protein source, the remainder of that protein becomes useless to human protein synthesis and has little nutritional value. As the FDA has explicitly recognized, "[b]ecause excess amino acids are not stored in the body, humans need a constant supply of good quality dietary proteins to support growth and development." 58 Fed. Reg. 2079 at 2101. High-quality proteins, therefore, are those that contain all nine essential amino acids because they have a greater effect on protein synthesis and are fully digestible. A dietary protein containing all of the essential amino acids in the correct proportions is typically called a "complete protein."
- 33. A protein source's digestibility also affects the amount of useable protein a person receives from consuming it. Plant-based proteins like chickpea, pea, and tapioca are less than 85% digestible, meaning 15% of the protein from that source will simply pass through the body without ever being absorbed at all.
- 34. As the FDA has stated in official guidance, "Accurate methods for determining protein quality are necessary because different food protein sources are not equivalent in their ability to support growth and body protein maintenance." 56 Fed. Reg. 60366, § B. The Protein Digestibility Corrected Amino Acid Score ("PDCAAS"), is the FDA mandated measure of

protein quality, and it accounts for both the amino acid profile and the digestibility of the protein. 21 C.F.R. § 101.9(c)(7)(ii).

- 35. The PDCAAS method requires the manufacturer to determine the amount of essential amino acids that the food contains and then combine that with the proteins' digestibility into an overall discount factor (i.e., a "score" from 0.0-1.0) that represents the actual amount of protein the food provides nutritionally when multiplied by raw protein quantity. The regulations term this the "corrected amount of protein per serving." 21 C.F.R. § 101.9(c)(7)(i).
- 36. Defendant uses plant-based proteins in its products. Because of the differences in benefits depending on the amino acid composition of a protein, the source of protein is important, protein does not contain all nine essential amino acids and is low quality to humans. Chickpea protein, pea protein, and tapioca typically have a PDCAAS of between .57 and .82, meaning only approximately 60-80% of the protein from those sources will be useable by humans as protein.
- 37. Accordingly, Defendant's use of low quality proteins means that they actually provide far less protein to humans than the Product labels claim.

#### Federal and State Regulations Governing Food Labeling

38. Identical federal and California laws regulate the content of labels on packaged food. The requirements of the Act, and its labeling regulations, including those set forth in 21 C.F.R. §§ 101, 102, were adopted by the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law"). California Health & Safety Code § 110100 ("All food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food labeling regulations of this state."). The federal laws and regulations discussed below are applicable nationwide to all sales of packaged food products. Additionally, none of the California laws sought to be enforced here imposes different requirements on the labeling of packaged food for sale in the United States.

 39. The Act, 21 U.S.C. § 343(a), and the Sherman Law, CITE, provides that a food is misbranded if "its labeling is false or misleading in any particular." PDCAAS for Protein

- 40. According to FDA regulations, "[a] statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as a Percent of Daily Value . . . shall be given if a protein claim is made for the product . . ." 21 C.F.R. 101.9(c)(7)(i) (emphasis added). If a manufacturer does not want to perform PDCAAS and provide a statement of the corrected amount of protein per serving in the NFP, then it shall not make any protein claims.
- 41. The regulation governing nutrient content claims, section 101.13, also makes this plain. Section 101.13(n) provides that "[n]utrition labeling in accordance with § 101.9 . . . shall be provided for any food for which a nutrient content claim is made" and § 101.13(b) states "a nutrient content claim[] may not be made on the label . . . unless the claim is made in accordance with this regulation [i.e., § 101.13] . . . ." In other words, a manufacturer may not make any protein nutrient content claims on the front labels of their products unless they have complied with the requirements for protein labeling in the nutrition facts panel pursuant to section 101.9(c)(7). Indeed, the FDA made clear when promulgating § 101.13(n) that it means that a manufacturer can only make "a nutrient content claim . . . on the label or in labeling of a food, provided that the food bears nutrition labeling that complies with the requirements in proposed § 01.9." 58 Fed. Reg. 2302, 23310.
- 42. Further, FDA regulations require the %DV for protein to be calculated using PDCAAS, a method that accounts for both protein quantity and protein quality. 21 C.F.R. § 101.9(c)(7)(i)-(iii); FDA Food Labeling Guide, p. 29, Question N.22.<sup>4</sup> The first step is to calculate the "corrected amount of protein per serving" by multiplying protein quantity by the

<sup>&</sup>lt;sup>4</sup> Guidance for Industry: A Food Labeling Guide ("FDA Food Labeling Guide") p. 29, Question N22, U.S. Food & Drug Administration, https://www.fda.gov/media/81606/download (last accessed February 18, 2020).

PDCAAS quality value, and then dividing that "corrected amount" by 50 grams (the "recommended daily value" for protein) to come up with the %DV. *Id*.

- 43. The Products all make protein claims on the front label, but fail, uniformly to provide a statement of the corrected amount of protein per serving in the NFP calculated according to the PDCAAS method. The protein claims on the front are, therefore, unlawful, and were never permitted to be on the labels in the first instance under §§ 101.9(c)(7)(i), 101.13(n), and 101.13(b).
- 44. Defendant's failure to include a statement of the corrected amount of protein perserving expressed as a %DV in the NFP also renders the NFP itself unlawful under §\$ 101.9(c)(7)(i)-(iii).
- 45. Defendant's use of a front-label protein claim, while failing to include the required statement of the corrected amount of protein per serving in the NFP calculated using the PDCAAS method and expressed as a %DV, is also misleading. By failing to provide it, Defendant misled consumers into believing that the Products provide a higher amount of protein than they really do. It also enabled Defendant to conceal the fact that its Products consist of low quality proteins derived from chickpea, pea, and tapioca that simply do not provide all of the protein that quantity alone represents. Indeed, when promulgating 21 C.F.R. § 101.9(c)(7), the FDA explained in published guidance that "Information on protein quantity alone can be misleading on foods that are of low protein quality." It also explained that it was prohibiting manufacturers from making any protein claims at all *unless* the manufacturer provides a statement of the corrected amount of protein per serving in the NFP based on PDCAAS because "nutrition labeling must allow consumers to readily identify foods with particularly low quality protein to prevent them from being misled by information on only the amount of protein present." 58 Fed. Reg. 2079 at 2101-2.
- 46. Similarly, 21 C.F.R. § 101.13(i)(3) prohibits manufacturers from making a claim on the front of a product's package about the "amount or percentage of a nutrient," such as protein, if the statement is "false or misleading in any respect." If it is, then "it may not be made on the label." 21 C.F.R. § 101.13(b). This is true even if the same amount appears in the

nutrition facts panel. 21 C.F.R. § 101.13(c). Since the omission of the %DV from the nutrition facts panel rendered the front label protein claim misleading, the protein claim was not permitted to be on the front label.

- 47. Under the Act, the term false has its usual meaning of "untruthful," while the term misleading is a term of art that covers labels that are technically true, but are likely to deceive consumers.
- 48. The FDA explained in promulgating section 101.13(i) that the regulation was necessary "since many consumers have a limited knowledge and understanding of the amounts of nutrients that are recommended for daily consumption," which means that "a statement declaring that the product contained a specified amount of a nutrient could be misleading. By its very presence, such a statement could give consumers who were unfamiliar with the dietary recommendations the false impression that the product would assist them in maintaining healthy dietary practices relative to the amount of the nutrient consumed when it, in fact, would not." 56 Fed. Reg. 60421. The rules are different for amounts in the NFP and nutrient content claims because a voluntary nutrient declaration on the front panel "is viewed by the agency as an effort to market the food as a significant source of nutrients." 56 Fed. Reg. 60366.
- 49. In addition to regulating the NFP, the FDA has promulgated a separate set of regulations that govern nutrient content claims on the front of a package. 21 C.F.R. § 101.13. A nutrient content claim is a claim that "expressly or implicitly characterizes the level of a nutrient." 21 C.F.R. § 101.13(b). "Express" nutrient content claims include any statement outside the Nutrition Facts Panel, about the level of a nutrient. 21 C.F.R. 101.13(b)(1); 21 C.F.R. § 101.13(c). Stating information from the nutrition facts panel (such as grams protein per serving) elsewhere on the package necessarily constitutes a nutrient content claim. 21 C.F.R. § 101.13(c). A manufacturer cannot make a nutrient content claim in the form of a "statement about the amount or percentage of a nutrient" if the statement is "false or misleading in any respect." 21 C.F.R. 101.13(i)(3).
- 50. While a required statement *inside* of the NFP escapes regulations reserved for nutrient content claims (21 C.F.R. § 101.13(c)), the identical statement *outside* of the NFP is

certain facts in the nutrition label is not a license to make that statement elsewhere on the product." *Reid v. Johnson & Johnson*, 780 F.3d 952, 960 (9th Cir. 2015). Thus, Defendant's quantitative protein claims on the front label are subject to analysis as a nutrient content claim and cannot be false or misleading in any manner.

- 51. Defendant's protein representations on the front package are misleading because they broadly tout protein quantity *alone* while ignoring that the poor quality proteins in the Products will provide far less useable protein than claimed. The claim on the front is therefore separately misleading and should never have appeared on the package.
- 52. Defendant's Products are unlawful, misbranded, and violate the Sherman Law, California Health & Safety Code § 110660, *et seq*. Defendant makes protein content claims on the front of its Product packages even though it uniformly fails to provide a statement of the corrected amount of protein per serving in the NFP calculated according to the PDCAAS method and expressed as a %DV as required by 21 C.F.R. § 101.9(c)(7)(i). Defendant's failure to comply with this requirement render its front label protein claim unlawful per se and the product misbranded pursuant to § 101.13(n) and (b), as well as under § 101.9(c)(7)(i) itself. Defendant's omission of the %DV from the NFP despite the fact that it makes front label protein claims is also unlawful and in violation of § 101.9(c)(7)(i)-(iii).
- 53. Defendant's standalone, front label protein quantity claim is also misleading, and therefore prohibited by sections 101.13(i)(3), (b), and (n) due to Defendant's failure to include a statement of the corrected amount of protein per serving in the NFP calculated using the PDCAAS method and expressed as a %DV. Consumers have a "limited knowledge and understanding of the amount of [protein] that [is] recommended for daily consumption," let alone an understanding of the science behind protein quality and how different types of proteins are used and absorbed in the body. 56 Fed. Reg. 60421. The FDA requires a statement of the corrected amount of protein per serving in the NFP precisely to ensure that "consumers are not misled by information on only the amount of protein present" in a product with low quality

4 5

protein. 58 Fed. Reg. 2079 at 2101-2. Defendant's failure to provide it rendered the label misleading. Further, the front label is also misleading because it states that it provides 8g protein per serving, when, in fact, after adjusting the protein content based on PDCAAS, the Products will provide approximately half that much protein.

#### **Fortification Policy**

- 54. The FDA has provided guidance that fortification of certain products, including snack foods, is not appropriate. 21 C.F.R. § 104.20 (the "Fortification Policy"). The Fortification Policy states that "The random fortification of foods . . . could result in deceptive and misleading claims."
- 55. Specifically, under the Fortification Policy, the FDA "does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify ... snack foods ...." See 21 C.F.R. § 104.20(a).
- 56. The Fortification Policy is a guidance that is binding in certain circumstances. For example, where a food advertises the fortification using words like "added," "plus," or other synonyms, the Policy is binding. *See* 21 C.F.R. 101.54(e). In this instance, the Products' packaging states "More protein" so the Fortification Policy is binding.
- 57. The Products violate the Fortification Policy because they do not meet any of the other conditions for fortification as provided in the Fortification Policy. *See* 21 C.F.R. § 104.20(b)-(e). The Products are therefore unlawfully fortified, and the Product labels contain prohibited nutritional claims.
- 58. As the FDA recognizes in its Fortification Policy, the fortification of foods that are otherwise not a significant source of nutrients is misleading and deceptive to consumers. The Products deceive consumers by implying representing that they contain "More protein," which suggests that the Products, because of their protein content, may help consumers meet their dietary and protein intake goals.
- 59. The FDA found that the Fortification Policy was necessary to address "the need to avoid adding certain nutrients to foods that are not appropriate vehicles for added nutrients." 44 Fed. Reg. 75990, 76010. The FDA stated that the Policy "should provide consumers with a

reasonable benefit . . . without misleading consumers into believing that the consumption of the fortified food per se will ensure a complete or nutritionally sound diet." 45 Fed. Reg. 6314. In establishing the Policy the FDA considered that "[o]verfortification in both quantity and kind of nutrients can lead to unusual and excessive intakes of some nutrients, particularly if it encourages consumption of a food which, by itself, may be considered to be nutritionally undesirable by . . . simply being a 'fun food.'" 43 Fed. Reg. 25296, 25305.

- 60. The FDA has described the purpose of nutrient content claim regulations to be "promoting sound nutrition for the nation's consumers." 56 Fed. Reg. 60421. The FDA relies on the USDA's development of Dietary Guidelines as the basis for encouraging and discouraging the "selection of foods containing low or high levels of certain nutrients as part of an overall diet." *Id*.
- 61. The 2020-2025 USDA Dietary Guidelines recommend "meeting food group needs with nutrient-dense foods and beverages" and "when deciding what to eat or drink, choose options that are full of nutrients." Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov (hereinafter "USDA Dietary Guidelines"). The Guidelines state that "the core elements that make up a healthy dietary pattern include . . . protein foods, including lean meats, poultry, and eggs; seafood; beans, peas, and lentils; and nuts, seeds, and soy products." *Id.* The Guidelines recommend meeting nutritional needs through consumption of *whole foods* and only recommends using fortified foods when meeting the dietary recommendation for that nutrient is "harder to achieve through natural sources from diet alone." Id. at 36 (emphasis added). For example, the Guidelines recommend supplementing diets with Vitamin D supplements for this reason. Fortification has also been found appropriate for folic acid to ensure women meet the recommended needs for the nutrient *Id.*
- 62. Protein is not a nutrient for which Americans are deficient. Most Americans meet their protein needs without supplementation. *See What We Eat in America*, Table 1. Available at https://www.ars.usda.gov/ARSUserFiles/80400530/pdf/1112/Table\_1\_NIN\_GEN\_11.pdf. On average, men and women over 20 years of age eat 98 grams and 68 grams of protein per day,

4

6

5

7 8

10

11

12 13

14

16

15

17 18

19

20 21

22

23

24 25

26

27

28

<sup>5</sup> https://a.co/d/5taNv5S

<sup>6</sup> https://www.mintel.com/press-centre/food-and-drink/43-of-us-cereal-consumers-eat-cereal-asa-snack-at-home

- respectively. *Id.* The Recommended Daily Intake for protein is 50 grams per day. 21 C.F.R. 101.9(c)(8).
- 63. The Products are snack products which the Policy specifically states should not be fortified. Defendant's online advertising claims that the Products are "an excellent breakfast or snack choice." And, a recent study confirmed that 43% of consumers eat cereal as a snack.6
- 64. The Products are not considered a "protein food" as defined by the USDA Dietary Guidelines, and are therefore discouraged for purposes of meeting protein needs.
- 65. Moreover, but for the fortification of the Products, the Products are nutritionally void. They offer little in contributing to a sound diet, with, for example, only 10% DV calcium and iron, 6% DV potassium, and no other nutrients. In the case of the Frosted Cereal, Honey Cereal, Cinnamon Cereal, Cocoa Cereal, and Fruity Cereal flavors of the Products, the Product has 3 grams of added sugar, which is harmful as it contributes to excess sugar intake and increased risk of diseases such as diabetes.
- 66. A reasonable consumer relies on the "more protein" representation and interprets it to mean the Products should be incorporated into their diet to meet their nutritional protein needs. However, the Products are not recommended for protein intake, are fortified in violation of the Fortification Policy, do not offer any other significant nutrients, and in some circumstances contribute to increased health risks from added sugar.
  - 67. Thus, the Products are misleading and therefore misbranded.

#### The Products' Labeling Violates Federal and State Regulations

68. Defendant's marketing, advertising, and sale of the Products violates the misbranding provisions of the Sherman Law (California Health & Safety Code § 110660, et seq.), including but not limited to:

- a. Section 110665 (a food is misbranded if its labeling does not conform with the requirements for nutrition labeling as set forth in 21 U.S.C. Sec. 343(q));
- Section 110705 (a food is misbranded if words, statements and other information required by the Sherman Law to appear food labeling is either missing or not sufficiently conspicuous);
- c. Section 110760, which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded;
- d. Section 110765, which makes it unlawful for any person to misbrand any food; and
- e. Section 110770, which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.
- 69. Defendant's marketing, advertising, and sale of the Products also violates the false advertising provisions of the Sherman Law (California Health & Safety Code § 110390, et seq.), including, but not limited to:
  - a. Section 110390, which makes it unlawful to disseminate false or misleading food advertisements that include statements on products and product packaging or labeling or any other medium used to directly or indirectly induce the purchase of a food product;
  - Section 110395, which makes it unlawful to manufacture, sell, deliver,
     hold or offer to sell any falsely or misleadingly advertised food; and
  - c. Sections 110398 and 110400, which make it unlawful to advertise misbranded food or to deliver or proffer for delivery any food that has been falsely or misleadingly advertised.
- 70. Defendant has violated the Act, and the standards set by FDA regulations, including but not limited to 21 C.F.R. § 101.9 (c)(7), 21 C.F.R. § 101.13(i)(3), (b), (n), 21 C.F.R. § 101.9(h)(d), and 21 C.F.R. 101.9(e)(3) which have been incorporated by reference in

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

the Sherman Law, by failing to include on the Product labels the nutritional information required by law.

- 71. A reasonable consumer would expect that the Products provide what Defendant identifies them to provide on the product labels and that the labels would not be contrary to the policies or regulations of the State of California and/or the FDA. For example, a reasonable consumer would expect that when Defendant labels its Products as containing "8g protein per serving," as Defendant claims on the Product, it would provide 8 grams of protein per serving in a form their bodies could use. Because Defendant did not conduct PDCAAS and provide a statement of the corrected amount of protein per serving, expressed as a %DV, consumers have no idea that the Products provide significantly less protein.
- 72. Consumers lack the meaningful ability to test or independently ascertain the truthfulness of Defendant's food labeling claims, especially at the point of sale. Reasonable consumers, when they look at the front label of the Products, believe the Products provide the amount of protein represented on the front label. Because Defendant does not include any information as to the quality of the protein anywhere on the packaging, even though it was legally required to do so via the statement of corrected amount of protein expressed as a %DV consumers do not have any reason to think otherwise. Reasonable consumers do not walk around with the PDCAAS values for various protein sources in their heads. They would not know the true amount of protein the Products provide nutritionally merely by looking elsewhere on the product package. Its discovery requires investigation well beyond the grocery store aisle and knowledge of food chemistry beyond that of the average consumer. An average consumer does not have the specialized knowledge necessary to ascertain that a serving of a Product does not provide the number of grams of protein that is represented on the label. An average consumer also lacks the specialized knowledge necessary to determine the PDCAAS for the Products. The average reasonable consumer had no reason to suspect that Defendant's representations on the packages were misleading. Therefore, consumers had no reason to investigate whether the Products actually do provide the amount of protein per serving that the

 the Products Actually Contain

profits.

labels claim they do and reasonably relied on Defendant's representations regarding the nature of the Products.

73. Defendant intends and knows that consumers will and do rely upon food labeling statements in making their purchasing decisions. Label claims and other forms of advertising and marketing drive product sales, particularly if placed prominently on the front of product packaging, as Defendant has done with the claims on the Products that they contain and provide specific amounts of protein per serving.

### <u>Defendant Misleadingly Markets the Products to Increase Profits and Gain a Competitive Edge</u>

74. In making unlawful, false, misleading, and deceptive representations, Defendant distinguishes the Products from its competitors' products. Defendant knew and intended that consumers would purchase, and pay a premium for, products labeled with protein claims. By using this branding and marketing strategy, Defendant is stating that the Products are superior to, better than, and more nutritious and healthful than other products that do not make protein claims, or that do not make protein claims based on poorly-disclosed added ingredients, or that properly provide the required statement of the corrected amount of protein in the product as determined by the PDCAAS method and express as a %DV and otherwise do not mislead consumers about the amount of protein their products actually provide.

# 75. Because consumers pay a price premium for products that make protein claims, and also pay a premium for products that provide more protein, by labeling its Products with protein claims and/or omitting the required statement of the corrected amount of protein per

Defendant Intends to Continue to Market the Products as Containing More Protein than

serving than they actually provide, Defendant is able to both increase its sales and retain more

76. Defendant engaged in the practices complained of herein to further its private interests of: (i) increasing sales of the Products while decreasing the sales of competitors that do not misrepresent the number of grams of protein contained in its products, and/or (ii) commanding a higher price for its Products because consumers will pay more for the Products

due to consumers' demand for products with protein claims and/or products fortified with protein.

- 77. The market for protein products is continuing to grow and expand, and because Defendant knows consumers rely on representations about the number of grams of protein in food products, Defendant has an incentive to continue to make such unlawful and misleading representations. In addition, other trends suggest that Defendant has no incentive to change its labeling practices.
- 78. For example, one market analysis revealed that between 2013-2017, product launches with a protein claim grew 31%.
- 79. To capitalize on the growing market, Defendant continues to launch new product lines and flavors to diversify its portfolio to maintain its competitive edge. Moreover, Defendant has continued to replicate its misrepresentations on new products. It is therefore likely that Defendant will continue to unlawfully and/or misleadingly advertise the Products and perpetuate the misrepresentations regarding the protein in the Products.

#### PLAINTIFF'S EXPERIENCES

- 80. On multiple occasions in the last four years, Plaintiff purchased the Three Wishes cereal in Unsweetened and Cocoa flavors from a Whole Foods retail store and online at Amazon.com.
- 81. Plaintiff made each of her purchases after reading and relying on the truthfulness of Defendant's front labels that promised the Products provided 8 grams of protein per serving and provide "More protein." She believed the truth of each representation, i.e., that the product would actually provide the specific amount of protein claimed on the front labels in a form human bodies could utilize. She relied on the Products to meet her protein dietary needs. Had Defendant complied with the law, and not made the protein claims on the front of its packages in these circumstances and not fortified its Products, she would not have been drawn to the

<sup>&</sup>lt;sup>7</sup> https://www.bakeryandsnacks.com/Article/2018/11/26/10-key-snack-trends-to-watch?utm\_source=copyright&utm\_medium=OnSite&utm\_campaign=copyright

Products and would not have purchased them. At a minimum, Plaintiff would have paid less for each Product.

- 82. Moreover, had Defendant adequately disclosed the corrected amount of protein per serving for each Product expressed as a %DV, as FDA regulations require, Plaintiff would not have purchased the Products or would have, at minimum, paid less for them. Plaintiff regularly checks the NFP before purchasing any product for the first time, including the %DV column for protein when manufacturers provide it, and she uses that information as a basis of comparison between similar products. She looked at and read the NFP on the Three Wishes Cereal before purchasing it for the first time. Manufacturers do not always disclose a %DV for protein, but when they do, she selects the product that provides more of the recommend daily amount of protein (i.e., the one with a higher %DV). When a manufacturer does not provide a %DV for protein, she can only go off of the stated grams of protein, and she assumes that all of those disclosed grams are in a form her body can use as protein.
- 83. For example, with the Unsweetened Three Wishes Cereal, Plaintiff was looking for a product that would provide 8 grams of useable protein per serving. Had she seen that the product provided only approximately 80% (or less) of the daily value for protein, i.e., only approximately 6 grams or less corrected amount of protein per serving, she would not have purchased the Products or, at a minimum, she would have paid less for them. Plaintiff would also have used the information as a basis to compare similar products and would have chosen instead to purchase one with a higher %DV. Without the statement of the corrected amount of protein per serving in the form of a %DV, the only information Plaintiff had about the Products was the 8g protein quantity, and she believed she was receiving the full amount of that quantity in a form human bodies could use. Because the Products did not provide any statement of the corrected amount of protein per serving, Plaintiff did not have any reason to believe that the Products provided less protein than the amount represented on the front of the label. Plaintiff did in fact believe she was receiving 8 grams of high quality protein when she purchased the Products.

84. Plaintiff continues to desire to purchase protein products, including those marketed and sold by Defendant, and would like to purchase products that provide 8 grams of protein per serving. If the Products were reformulated to provide, in a usable form, the grams of protein that are represented on the labels, or the labels were reformulated to provide nonmisleading information, Plaintiff would likely purchase them again in the future. Plaintiff regularly visits stores where the Products and other protein products are sold. Because Plaintiff does not know the formula for Defendant's products, which can change over time, and cannot test whether the Products provide the amount of digestible protein that is represented on the label without first purchasing the Product, Plaintiff will be unable to rely on Defendant's label\$ when shopping for protein products in the future absent an injunction that prohibits Defendant from mislabeling its Products. Plaintiff would also be forced to retest and/or reanalyze each Product at each time of purchase because a Product's ingredient list and labeling would not reveal any changes in the amount of digestible protein, even if such changes took place. In addition, at present Plaintiff cannot rely on the accuracy of Defendant's labels for the entire line of Products, which Plaintiff is also interested in purchasing with labeling that comports with regulations. Should Defendant begin to market and sell a new line of products, Plaintiff could also be at risk for buying another one of Defendant's products in reliance on the same or similar misrepresentation and omissions. And because of Defendant's unlawful and misleading labels on its Products, Plaintiff cannot make informed choices between protein products offered by Defendant and protein products offered by other manufacturers, such as choices based on price and relative nutritional content.

85. Plaintiff and members of the Class have been economically damaged by their purchase of the Products because the advertising for the Products was and is untrue and/or misleading under state law and the products are misbranded; therefore, the Products are worth less than what Plaintiff and members of the Class paid for them and/or Plaintiff and members of the Class did not receive what they reasonably intended to receive.

#### **CLASS ALLEGATIONS**

21

22

23

24

25

26

6

8 9

11 12

14

15

13

16 17

18

20

19

21 22

23

24

25 26

27

28

86. Plaintiff brings this class action lawsuit on behalf of herself and a proposed class of similarly situated persons, pursuant to Rule 23(b)(2) and (b)(3) of the Federal Rules of Civi Procedure. Plaintiff seeks to represent the following group of similarly situated persons, defined as follows:

The Class: All persons in the State of California who purchased the Products between August 19, 2018 and the present.

- 87. This action has been brought and may properly be maintained as a class action against Defendant because there is a well-defined community of interest in the litigation and the proposed class is easily ascertainable.
- 88. Numerosity: Plaintiff does not know the exact size the Class, but she estimates that it is composed of more than 100 persons. The persons in the Class are so numerous that the joinder of all such persons is impracticable and the disposition of their claims in a class action rather than in individual actions will benefit the parties and the courts.
- 89. Common Questions Predominate: This action involves common questions of law and fact to the potential Class because each class member's claim derives from the deceptive unlawful and/or unfair statements and omissions that led consumers to believe that the Products contained the amount of protein as represented on the Product labels. The common questions of law and fact predominate over individual questions, as proof of a common or single set of facts will establish the right of each member of the Class to recover. The questions of law and fac common to the Class are:
  - What is the PDCAAS for the protein in the Products; a.
  - Whether the marketing, advertising, packaging, labeling, and other b. promotional materials for the Products are unlawful and/or misleading;
  - Whether the fortification of the Products is unlawful: c.
  - d. Whether Defendant's actions violate Federal and California laws invoked herein;
  - Whether labeling the Products with a protein claim causes the Products to e. command a price premium in the market;

- f. Whether Defendant's failure to provide a statement of the corrected amount of protein per serving in the Products sold to the Class and Subclass members was likely to deceive reasonable consumers;
- g. Whether the fortification of the Products is unlawful;
- h. Whether representations regarding the number of grams of protein in the Products are material to a reasonable consumer;
- Whether Defendant engaged in the behavior knowingly, recklessly, or negligently;
- The amount of profits and revenues Defendant earned as a result of the conduct;
- k. Whether Class members are entitled to restitution, injunctive and other equitable relief and, if so, what is the nature (and amount) of such relief, and
- 1. Whether Class members are entitled to payment of actual, incidental, consequential, exemplary and/or statutory damages plus interest thereon, and if so, what is the nature of such relief.
- 90. Typicality: Plaintiff's claims are typical of the claims of the other members of the Class because, among other things, all such claims arise out of the same wrongful course of conduct engaged in by Defendant in violation of law as complained of herein. Further, the damages of each member of the Class were caused directly by Defendant's wrongful conduct in violation of the law as alleged herein.
- 91. Adequacy of Representation: Plaintiff will fairly and adequately protect the interests of all Class members because it is in their best interests to prosecute the claims alleged herein to obtain full compensation due to them for the unfair and illegal conduct of which they complain. Plaintiff also has no interests that are in conflict with, or antagonistic to, the interests of Class members. Plaintiff has retained highly competent and experienced class action attorneys to represent her interests and that of the Class. By prevailing on her own claims, Plaintiff will establish Defendant's liability to all Class members. Plaintiff and her counsel have

the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiff and counsel are aware of their fiduciary responsibilities to the Class members and are determined to diligently discharge those duties by vigorously seeking the maximum possible recovery for Class members.

- 92. Superiority: There is no plain, speedy, or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by members of the class will tend to establish inconsistent standards of conduct for Defendant and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Furthermore, as the damages suffered by each individual member of the class may be relatively small, the expenses and burden of individual litigation would make it difficult or impossible for individual members of the class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action.
- 93. Plaintiff is unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

#### **CAUSES OF ACTION**

Plaintiff does not plead, and hereby disclaims, causes of action under the FDCA and regulations promulgated thereunder by the FDA. Plaintiff relies on the FDCA and FDA regulations only to the extent such laws and regulations have been separately enacted as state law

or regulation or provide a predicate basis of liability under the state and common laws cited in the following causes of action.

#### PLAINTIFF'S FIRST CAUSE OF ACTION

(Violation of the Consumers Legal Remedies Act (the "CLRA"), California Civil Code § 1750, et seq.)

On Behalf of Plaintiff and the Class

- 2
- 3 4
- 56

- 8 9
- 11

10

- 12 13
- 15

- 16 17
- 18
- 19
- 2021
- 22
- 2324
- 25
- 26
- 2728

- 94. Plaintiff realleges and incorporates the paragraphs of this Class Action Complaint as if set forth herein.
- 95. Defendant's actions, representations and conduct have violated, and continue to violate the CLRA, because they extend to transactions that are intended to result, or which have resulted, in the sale or lease of goods or services to consumers.
- 96. Plaintiff and other class members are "consumers" as that term is defined by the CLRA in California Civil Code § 1761(d).
- 97. The Products that Plaintiff (and other similarly situated class members purchased from Defendant were "goods" within the meaning of California Civil Code § 1761(a).
- 98. Defendant's acts and practices, set forth in this Class Action Complaint, led customers to falsely believe that the Products provided nutritionally the amount of protein claimed on the product package. By engaging in the actions, representations and conduct set forth in this Class Action Complaint, Defendant has violated, and continues to violate, 1770(a)(2), § 1770(a)(5), § 1770(a)(7), § 1770(a)(8), and § 1770(a)(9) of the CLRA. In violation of California Civil Code §1770(a)(2), Defendant's acts and practices constitute improper representations regarding the source, sponsorship, approval, or certification of the goods they sold. In violation of California Civil Code §1770(a)(5), Defendant's acts and practices constitute improper representations that the goods it sells have sponsorship, approval characteristics, ingredients, uses, benefits, or quantities, which they do not have. In violation of California Civil Code §1770(a)(7), Defendant's acts and practices constitute improper representations that the goods it sells are of a particular standard, quality, or grade, when they are of another. In violation of California Civil Code §1770(a)(8), Defendant deceptively markets and advertises that, unlike other protein product manufacturers, it sells Products that provide more grams of protein than the Products actually do. In violation of California Civil Code §1770(a)(9), Defendant has advertised goods or services with intent not to sell them as advertised. Finally, Defendant had a duty to disclose the corrected amount of protein per serving

in the NFP as calculated by the PDCAAS method, which Defendant failed to do. 21 C.F.R. § 101.9(c)(7)(i)-(iii).

- 99. Plaintiff requests that this Court enjoin Defendant from continuing to employ the unlawful methods, acts and practices alleged herein pursuant to California Civil Code § 1780(a)(2). If Defendant is not restrained from engaging in these types of practices in the future, Plaintiff and the other members of the Class will continue to suffer harm. Plaintiff and those similarly situated have no adequate remedy at law to stop Defendant's continuing practices.
- 100. Plaintiff provided Defendant with notice and a demand to Defendant correct, repair, replace or otherwise rectify the unlawful, unfair, false and/or deceptive practices complained of herein. Despite receiving the aforementioned notice and demand, Defendant failed to do so in that, among other things, it failed to identify similarly situated customers, notify them of their right to correction, repair, replacement or other remedy, and/or to provide that remedy. Accordingly, Plaintiff seeks, pursuant to California Civil Code § 1780(a)(3), on behalf of themselves and those similarly situated class members, compensatory damages, punitive damages and restitution of any ill-gotten gains due to Defendant's acts and practices.
- 101. Plaintiff also requests that this Court award her costs and reasonable attorneys fees pursuant to California Civil Code § 1780(d).

#### PLAINTIFF'S SECOND CAUSE OF ACTION

#### (False Advertising, Business and Professions Code § 17500, et seq. ("FAL")) On Behalf of Plaintiff and the Class

- 102. Plaintiff realleges and incorporates by reference the paragraphs of this Class Action Complaint as if set forth herein.
- 103. Beginning at an exact date unknown to Plaintiff, but within four (4) years preceding the filing of the Class Action Complaint, Defendant made untrue, false, deceptive and/or misleading statements in connection with the advertising and marketing of the Products.
- 104. Defendant made representations and statements (by omission and commission) that led reasonable customers to believe that the Products that they were purchasing contained more grams of protein per serving than the Products actually provided, and that the Products

were appropriate for meeting protein dietary needs. Defendant had a duty to disclose the corrected amount of protein per serving in the NFP, as calculated according to the PDCAAS method, which Defendant failed to do. Defendant was also prohibited from fortifying its snack Products.

- 105. Plaintiff and those similarly situated relied to their detriment on Defendant's false, misleading and deceptive advertising and marketing practices, including each of the misrepresentations and omissions set forth above. Had Plaintiff and those similarly situated been adequately informed and not intentionally deceived by Defendant, they would have acted differently by, without limitation, refraining from purchasing Defendant's Products or paying less for them.
  - 106. Defendant's acts and omissions are likely to deceive the general public.
- 107. Defendant engaged in these false, misleading and deceptive advertising and marketing practices to increase its profits. Accordingly, Defendant has engaged in false advertising, as defined and prohibited by section 17500, *et seq.* of the California Business and Professions Code.
- 108. The aforementioned practices, which Defendant used, and continues to use, to its significant financial gain, also constitute unlawful competition and provide an unlawful advantage over Defendant's competitors as well as injury to the general public.
- 109. As a direct and proximate result of such actions, Plaintiff and the other members have suffered, and continue to suffer, injury in fact and have lost money and/or property as a result of such false, deceptive and misleading advertising in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court.
- 110. Plaintiff seeks, on behalf of herself and those similarly situated, full restitution of monies, as necessary and according to proof, to restore any and all monies acquired by Defendant from Plaintiff, the general public, or those similarly situated by means of the false, misleading and deceptive advertising and marketing practices complained of herein, plus interest thereon. Pursuant to Federal Rule of Civil Procedure 8(e)(2), Plaintiff makes the following allegations in this paragraph only hypothetically and as an alternative to any contrary

1 all
2 Pla
3 din
4 rec
5 co
6 Cl
7 de
8 inj
9 (N
10 inc
11 ma
12 rei
13 an

allegations in her other causes of action, in the event that such causes of action will not succeed. Plaintiff and the Class may be unable to obtain monetary, declaratory and/or injunctive relief directly under other causes of action and will lack an adequate remedy at law, if the Court requires them to show classwide reliance and materiality beyond the objective reasonable consumer standard applied under the FAL, because Plaintiff may not be able to establish each Class member's individualized understanding of Defendant's misleading representations as described in this Complaint, but the FAL does not require individualize proof of deception or injury by absent Class members. *See, e.g., Ries v. Ariz. Bevs. USA LLC*, 287 F.R.D. 523, 537 (N.D. Cal. 2012) ("restitutionary relief under the UCL and FAL 'is available without individualized proof of deception, reliance, and injury.""). In addition, Plaintiff and the Class may be unable to obtain such relief under other causes of action and will lack an adequate remedy at law, if Plaintiff is unable to demonstrate the requisite *mens rea* (intent, reckless, and/or negligence), because the FAL imposes no such *mens rea* requirement and liability exists even if Defendant acted in good faith.

111. Plaintiff seeks, on behalf of herself and those similarly situated, a declaration that the above-described practices constitute false, misleading and deceptive advertising.

112. Plaintiff seeks, on behalf of herself and those similarly situated, an injunction to prohibit Defendant from continuing to engage in the false, misleading and deceptive advertising and marketing practices complained of herein. Such misconduct by Defendant, unless and until enjoined and restrained by order of this Court, will continue to cause injury in fact to the general public and the loss of money and property in that Defendant will continue to violate the laws of California, unless specifically ordered to comply with the same. This expectation of future violations will require current and future consumers to repeatedly and continuously seek legal redress in order to recover monies paid to Defendant to which it is not entitled. Plaintiff, those similarly situated, and/or other consumers nationwide have no other adequate remedy at law to ensure future compliance with the California Business and Professions Code alleged to have been violated herein.

### 

# 3 4

#### PLAINTIFF'S THIRD CAUSE OF ACTION

### (Common Law Fraud, Deceit and/or Misrepresentation) On Behalf of Plaintiff and the Class

- 113. Plaintiff realleges and incorporates by reference the paragraphs of this Class Action Complaint as if set forth herein.
- 114. Defendant has fraudulently and deceptively informed Plaintiff that the Products provide more grams of protein than they actually provide in a form useful to the human body. Defendant failed to provide a statement of the corrected amount of protein per serving in the NFP, calculated according to the PDCAAS method, on all the Products, as it was required to do. Defendant was also prohibited from fortifying its snack Products.
- 115. These misrepresentations and omissions were known exclusively to, and actively concealed by, Defendant, not reasonably known to Plaintiff, and material at the time they were made. Defendant knew or should have known the composition of the Products, and knew or should have known that the Products did not contain or provide the amount of protein represented on the label, and knew or should have known that the Products could not be fortified in this manner. Defendant's misrepresentations and omissions concerned material facts that were essential to the analysis undertaken by Plaintiff as to whether to purchase Defendant's Products. In misleading Plaintiff and not so informing Plaintiff, Defendant breached its duty to them. Defendant also gained financially from, and as a result of, its breach.
- 116. Plaintiff and those similarly situated relied to their detriment on Defendant's misrepresentations and fraudulent omissions. Had Plaintiff and those similarly situated been adequately informed and not intentionally deceived by Defendant, they would have acted differently by, without limitation: (i) declining to purchase the Products, (ii) purchasing less of them, or (iii) paying less for the Products.
- 117. By and through such fraud, deceit, misrepresentations and/or omissions, Defendant intended to induce Plaintiff and those similarly situated to alter their position to their detriment. Specifically, Defendant fraudulently and deceptively induced Plaintiff and those similarly situated to, without limitation, purchase the Products.

- 118. Plaintiff and those similarly situated justifiably and reasonably relied on Defendant's misrepresentations and omissions, and, accordingly, were damaged by Defendant.
- 119. As a direct and proximate result of Defendant's misrepresentations and/or omissions, Plaintiff and those similarly situated have suffered damages, including, without limitation, the amount they paid for the Products.
- 120. Defendant's conduct as described herein was wilful and malicious and was designed to maximize Defendant's profits even though Defendant knew that it would cause loss and harm to Plaintiff and those similarly situated.

#### PLAINTIFF'S FOURTH CAUSE OF ACTION

#### (Unlawful, unfair, and fraudulent trade practices violation of Business and Professions Code § 17200, et seq.) On Behalf of Plaintiff and the Class

- 121. Plaintiff realleges and incorporates by reference the paragraphs of this Class Action Complaint as if set forth herein.
- 122. Within four (4) years preceding the filing of this lawsuit, and at all times mentioned herein, Defendant has engaged, and continue to engage, in unlawful, unfair, and fraudulent trade practices in California by engaging in the unlawful, unfair, and fraudulent business practices outlined in this complaint.
- 123. In particular, Defendant has engaged, and continues to engage, in unlawful practices by, without limitation, violating the following state and federal laws: (i) the CLRA as described herein; (ii) the FAL as described herein; (iii) the advertising provisions of the Sherman Law (Article 3), including without limitation, California Health & Safety Code §\$ 110390, 110395, 110398 and 110400; (iv) the misbranded food provisions of the Sherman Law (Article 6), including without limitation, California Health & Safety Code §\$ 110660, 110665, 110705, 110760, 110765, and 110770; and (v) and federal laws regulating the advertising and branding of food in 21 U.S.C. § 343(a), *et seq.* and FDA regulations, including but not limited to 21 C.F.R. 21 C.F.R. § 101.9 (c)(7), which are incorporated into the Sherman Law (California Health & Safety Code §\$ 110100(a), 110380, and 110505).

In particular, Defendant has engaged, and continues to engage, in unfair and

124.

- fraudulent practices by, without limitation, the following: (i) unlawfully making a protein claim on the front of the package without complying with the regulatory requirements for making a protein claim set forth in 21 C.F.R. § 101.9(c)(7)(i)-(iii) and incorporated by reference by California's Sherman law; (ii) failing to provide a statement of the corrected amount of protein per serving in the NFP, calculated according to the PDCAAS method and expressed as a %DV, as required by FDA regulations; (iii) misleading reasonable consumers regarding the amount of protein the Products provide nutritionally in a form that humans can use; and (iv) fortifying its snacks in violation of FDA guidance and regulations.
- 125. Plaintiff and those similarly situated relied to their detriment on Defendant's unlawful, unfair, and fraudulent business practices. Had Plaintiff and those similarly situated been adequately informed and not deceived by Defendant, they would have acted differently by, without limitation: (i) declining to purchase the Products, (ii) purchasing less of the Products, or (iii) paying less for the Products.
  - 126. Defendant's acts and omissions are likely to deceive the general public.
- 127. Defendant engaged in these deceptive and unlawful practices to increase its profits. Accordingly, Defendant has engaged in unlawful trade practices, as defined and prohibited by section 17200, *et seq.* of the California Business and Professions Code.
- 128. The aforementioned practices, which Defendant has used to its significant financial gain, also constitute unlawful competition and provide an unlawful advantage over Defendant's competitors as well as injury to the general public.
- 129. As a direct and proximate result of such actions, Plaintiff and the other Class members have suffered and continue to suffer injury in fact and have lost money and/or property as a result of such deceptive and/or unlawful trade practices and unfair competition in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court. Among other things, Plaintiff and the Class members lost the amount they paid for the Products.

12

9

17 18

16

20

21

19

2223

2425

2627

28

130. As a direct and proximate result of such actions, Defendant has enjoyed, and continues to enjoy, significant financial gain in an amount which will be proven at trial, but which is in excess of the jurisdictional minimum of this Court.

- 131. Plaintiff seeks, on behalf of themselves and those similarly situated, equitable relief, including the restitution for the premium and/or full price that they or others paid to Defendant as a result of Defendant's conduct. Plaintiff and the Class lack an adequate remedy at law to obtain such relief with respect to their "unlawfulness" claims in this UCL cause of action because the California Sherman Law does not provide a direct cause of action, so Plaintiff and the Class must allege those violations as predicate acts under the UCL to obtain relief.
- 132. Plaintiff also seeks equitable relief, including restitution, with respect to her UCL "fraudulent" prong claims. Pursuant to Federal Rule of Civil Procedure 8(e)(2), Plaintiff makes the following allegations in this paragraph only hypothetically and as an alternative to any contrary allegations in their other causes of action, in the event that such causes of action do not succeed. Plaintiff and the Class may be unable to obtain monetary, declaratory and/or injunctive relief directly under other causes of action and will lack an adequate remedy of law, if the Court requires them to show classwide reliance and materiality beyond the objective reasonable consumer standard applied under the UCL, because Plaintiff may not be able to establish each Class member's individualized understanding of Defendant's misleading representations as described in this Complaint, but the UCL does not require individualized proof of deception of injury by absent class members. See, e.g., Stearns v Ticketmaster, 655 F.3d 1013, 1020, 1023 25 (distinguishing, for purposes of CLRA claim, among class members for whom website representations may have been materially deficient, but requiring certification of UCL claim for entire class). In addition, Plaintiff and the Class may be unable to obtain such relief under other causes of action and will lack an adequate remedy at law, if Plaintiff is unable to demonstrate the requisite *mens rea* (intent, reckless, and/or negligence), because the UCL imposes no such mens rea requirement and liability exists even if Defendant acted in good faith.
- 133. Plaintiff seeks, on behalf of those similarly situated, a declaration that the above-described trade practices are fraudulent, unfair, and/or unlawful.

Defendant from continuing to engage in the deceptive and/or unlawful trade practices complained of herein. Such misconduct by Defendant, unless and until enjoined and restrained by order of this Court, will continue to cause injury in fact to the general public and the loss of money and property in that Defendant will continue to violate the laws of California, unless specifically ordered to comply with the same. This expectation of future violations will require current and future consumers to repeatedly and continuously seek legal redress in order to recover monies paid to Defendant to which they were not entitled. Plaintiff and those similarly situated have no other adequate remedy at law to ensure future compliance with the California Business and Professions Code alleged to have been violated herein.

# PLAINTIFF'S FIFTH CAUSE OF ACTION (Unjust Enrichment) On Behalf of Plaintiff and the Class

- 135. Plaintiff realleges and incorporate by reference the paragraphs of this Class Action Complaint as if set forth herein.
- 136. Plaintiff and members of the Class conferred a benefit on the Defendant by purchasing the Products.
- 137. Defendant has been unjustly enriched in retaining the revenues from Plaintiff's and Class members' purchases of the Products, which retention is unjust and inequitable, because Defendant falsely represented that the Products contained specific amounts of protein per serving, while failing to disclose that the Products actually provided less protein than represented. Further, Defendant fortified the Products with "More protein" despite FDA guidelines that provide that snack foods should not be fortified with nutrients. This harmed Plaintiff and Class members because they paid a price premium as a result.
- 138. Because Defendant's retention of the non-gratuitous benefit conferred on it by Plaintiff and Class members is unjust and inequitable, Defendant must pay restitution to Plaintiff and the Class members for its unjust enrichment, as ordered by the Court. Plaintiff and those similarly situated have no adequate remedy at law to obtain this restitution.

1	139. Plaintiff, therefore, seeks an order requiring Defendant to make restitution			
2	them and other members of the Class.			
3	PRAYER FOR RELIEF			
4	WHEREFORE, Plaintiff, on behalf of herself and those similarly situated, respectful			
5	request that the Court enter judgement against Defendant as follows:			
6	A. Certification of the proposed Class, including appointment of Plaintiff's couns			
7	as class counsel;			
8	B. An order temporarily and permanently enjoining Defendant from continuing t			
9	unlawful, deceptive, fraudulent, and unfair business practices alleged in this Complaint;			
10	C. An award of compensatory damages in an amount to be determined at tri			
11	except for those causes of action where compensatory damages are not legally available;			
12	D. An award of statutory damages in an amount to be determined at trial, except f			
13	those causes of action where statutory damages are not legally available;			
14	E. An award of punitive damages in an amount to be determined at trial, except f			
15	those causes of action where punitive damages are not legally available;			
16	F. An award of treble damages, except for those causes of action where treb			
17	damages are not legally available;			
18	G. An award of restitution in an amount to be determined at trial;			
19	H. An order requiring Defendant to pay both pre- and post-judgment interest on a			
20	amounts awarded;			
21	I. For reasonable attorneys' fees and the costs of suit incurred; and			
22	J. For such further relief as this Court may deem just and proper.			
23	JURY TRIAL DEMANDED			
24	Plaintiff hereby demands a trial by jury.			
25	Dated: August 19, 2022			
26				
27				
28				

#### **GUTRIDE SAFIER LLP**

/s/Seth A. Safier/s/

Seth A. Safier (State Bar No. 197427) seth@gutridesafier.com
Marie A. McCrary (State Bar No. 262670) marie@gutridesafier.com
Hayley Reynolds (State Bar No. 306427) hayley@gutridesafier.com
100 Pine Street, Suite 1250
San Francisco, California 94111
Telephone: (415) 639-9090
Facsimile: (415) 449-6469

Attorneys for Plaintiff

EXHIBIT A I, Lydia Harville, declare: 1. I am a Plaintiff in this action. If called upon to testify, I could and would competently testify to the matters contained herein based upon my personal knowledge. 2. I submit this Declaration pursuant to California Code of Civil Procedure section 2215.5 and California Civil Code section 1780(d). 3. As set forth in my complaint, I purchased Three Wishes Cereal in the Unsweetened and Cocoa flavors on multiple occasions during the last four years from Amazon.com and a Whole Foods retail store in California. I declare under penalty of perjury under the laws of California that the foregoing is true and correct. Executed on August 9, 2022, in Los Gatos, California. 

#### EXHIBIT B

<b>Product Type</b>	Variety	Protein Content Claim
Cereal	Three Wishes Cinnamon Cereal	8g (No DV)
	Three Wishes Honey Cereal	8g (No DV)
	Three Wishes Unsweetened Cereal	8g (No DV)
	Three Wishes Cocoa Cereal	8g (No DV)
	Three Wishes Fruity Cereal	8g (No DV)
	Three Wishes Frosted Cereal	8g (No DV)
	Three Wishes Buddy Cereal	8g (No DV)